

IP Policy For Businesses: State Should Hold Patents; AG Needs Enforcer Role

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Who we are

- FTCR is a non-profit, non-partisan consumer watchdog organization.
- Proposition 103 -- reformed insurance industry.
- Authored Patient's Bill Of Rights legislation.
- No position on Prop. 71; when passed began work to ensure public benefit promises are kept.
- John M. Simpson: veteran journalist; USA Today deputy editor, edited international edition; taught journalism in Ireland.

Ignore the biotech bluster

- Some biotech executives threaten to pick up Petri dishes and go home. Don't believe it.
- Venture capitalists have referred to Prop 71 grants as “almost like free money.”
- Venture capitalists invested only \$120 million of \$5.9 billion to biotech in stem cell research last year. Federal government funded \$30 million -- *San Diego Union Tribune*.
- CIRM with \$300 million plus a year is likely to be the world's biggest of stem cell funds.

Promise of Proposition 71

- “Protect and benefit the California budget... by providing an opportunity for the state to benefit from royalties, patents and licensing fees that result from research.” --Sec. 3, Purpose & Intent, Prop 71
- Supporters estimated \$6.4 to \$12.6 billion in revenues and savings to the state.
- Overwhelming support for Prop 71, but not a blank check for biotech.
- IP policy key to fulfilling public benefit promise.

Prop 71 Money: Scenario 1

- Grant: Like building a house.
- You pay the builder and own the house.
- Same with Prop 71 money. Taxpayers should own any discoveries.
- State holds patent.
- Usually in patent pool.
- Could license back exclusively to grantee if necessary to commercialize.

Prop 71 Money: Scenario 2

- Grant, but a partnership.
- Builder owns the land, you put up money. When house is sold, you get share.
- With Prop 71, biotech firm already has patent or license; gets grant.
- If there is revenue resulting , state should get share.

Prop 71 Money: Scenario 3

- Loan: Works just like a bank loan
- Paid back with interest over agreed time.
- A mortgage lender places requirements on borrower such as need for insurance.
- CIRM places public benefit requirements on borrowers of Prop 71 funds.

Prop 71 Money: Scenario 4

- Contract for specific service.
- Like hiring someone to clean your house.
- Perhaps maintaining a stem cell bank.
- Perhaps providing some some widely required research tool.
- Public benefit requirement part of the award process.

Three IP policy principles

- **Affordability**-- Cures treatments must be priced so all Californians can afford and benefit from them, not just a wealthy few.
- **Accessibility** -- Not only do all Californians deserve access to Proposition 71-funded therapies, but stem cell researchers also need access to the results of other Proposition 71-funded research to develop the widest range of cures.
- **Accountability** -- Policies must ensure that grantees and licensees fulfill their obligations when benefiting from public money.

Affordability

- A business receiving Prop 71 funding must sell any therapies and diagnostics at a reasonable price. A reasonable price reflects the true cost of development and the public's investment.
- Businesses must pay the state 25 percent of any net royalties they receive for any invention or discovery developed with Prop 71 funds.

Affordability

- Businesses receiving grants must pay a commission on gross sales of any Prop 71 funded drug or cure at the UC rate.
- Businesses receiving grants or loans must be required to explain how any discovery would be managed to benefit all Californians.
- A business receiving Proposition 71 funding must agree to sell all its therapies and diagnostics to publicly funded health plans in California at its lowest price.

Accessibility

- CIRM should create a patent pool that would include patents resulting from research it funds, including businesses. A three-person board including the AG would govern the pool.
- A business receiving Prop 71 funding must provide access to resultant therapies and diagnostics for uninsured patients.
- CIRM could bar any discovery from being licensed exclusively.

Accessibility

- Any California-based researcher should be able to use the results of CIRM-funded research for further research without paying a licensing fee.
- When granting an exclusive license to bring a particular drug or treatment to market, it should be issued on a disease specific basis.

Accountability

- The California Attorney General must have “march-in rights” -- the ability to intervene -- if a drug or therapy based on CIRM-funded research were priced unreasonably.
- The AG must have march-in rights if any other public benefit requirement were not met.
- CIRM should have march-in rights to take control of a CIRM-funded discovery if a business failed to develop it.

Accountability

- CIRM must have march-in rights for public health and safety reasons, for instance meeting the public need of getting vaccines to market.
- All investors and major shareholders in start-up companies resulting from Proposition 71-funded research must file disclosure forms with CIRM. These would be public records.

In summary:

- IP rules are the means to keep promise of public benefit.
- State should hold the patent.
- Rules must require reasonable prices.
- Non-profit IP rules need improvement, but are a minimum starting point.
- What venture capitalists call “free money” must come with public benefit requirements.



Thank you.

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